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EXAMINER

THANGAVELU, KANDASAMY

ART UNIT	PAPER NUMBER
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2123

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,684

Applicant(s)

ASCENZI, MARIA-GRAZIA

Examiner

Kandasamy Thangavelu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>15 November 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This communication is in response to the Applicants' Amendment dated November 15, 2004. Claims 1-3 were amended. Claims 6-9 were added. Claims 1-9 of the application are pending. This office action is made final.

Drawings

2. The drawings submitted on November 15, 2004 are objected to. The bottom margins in Figures 3B, 4C, 6B and 6C, 7B, 8D and 12B are inadequate. A minimum of 1 cm margin is required at the bottom of all drawings. Applicant is required to send corrected drawings in response to this office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4.1 Claim 5 states, "A model of macrostructural characteristics of a bone and interactions of the bone with external force comprising at least three orders of hierarchical structural and hierarchical mechanical properties of microstructure of the bone, wherein:

a first order comprises at least one macroscopic region of the bone,

a second order comprises at least one component representing one or more osteons or lamellae,

a third order comprises at least one component representing one or more collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, or combinations thereof,

each component is correlated with at least one mechanical property,

components of the third order are assembled to provide a description of components of the second order, and

components of the second order are assembled to provide a description of one or more characteristics of the first order, including at least one interaction with an external force".

The statement "three orders of hierarchical structural and hierarchical mechanical properties of *microstructure of the bone* wherein a first order comprises at least *one macroscopic region of the bone*" does not make sense. Does this mean that one of the three orders of the microstructure of the bone includes the macrostructure of the bone? The specification Para 0003 states that the adult bone has four order hierarchy arranged in decreasing

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size; the first order macrostructure comprises structures corresponding to gross shape... the second order (or microstructure) of the compact bone includes lamellar systems... the third order (or ultrastructure) of the compact bone consists mainly of collagen bundles and hydroxyapatite crystallites...the fourth order of the compact bone consists of molecular arrangements. In view of this description of the four order structure of the bone, there is no support for “three orders of hierarchical structural and hierarchical mechanical properties of *microstructure of the bone* wherein a first order comprises at least *one macroscopic region of the bone*” in the specification.

4.2 Claim 6 states in part, “comparing the model of macrostructural characteristics of the bone with a subject bone”. This does not make sense. The model of macrostructural characteristics of the bone is a mathematical model consisting of equations. How can one compare the mathematical equations written on a paper to the subject bone or an actual or real or human bone? The specification does not explain how the mathematical model of the bone is compared to the actual bone. The model could also be a computer model written as software. The claim does not state that. Even if it were a computer model, the computer model cannot be compared to an actual bone. How do you compare the software in the computer to a bone in the human body?

Claim 6 states in part, “predicting deformation or fractures of the subject bone based upon the differences in the model of bone and the subject bone”. What is meant by differences in the model of the bone and the subject of the bone? As explained in the paragraph above, a model of the bone which is a mathematical model or a software model cannot be compared to an

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actual bone. How does one determine the differences between a model of the bone and an actual bone?

4.3 Claim 7 states in part, “comparing the model of macrostructural characteristics of the bone with a synthetic bone”. This does not make sense. The model of macrostructural characteristics of the bone is a mathematical model consisting of equations. How can one compare the mathematical equations written on a paper to the synthetic bone made of some bone making materials? The specification does not explain how the mathematical model of the bone is compared to the synthetic bone. The model could also a computer model written as software. The claim does not state that. Even if it were a computer model, the computer model cannot be compared to a synthetic bone. How do you compare the software in the computer to a bone made of some bone making materials? It is also not clear if the applicant meant to say synthetic bone or a model of the synthetic bone. What is the basis for comparing the model of the bone with the model of the synthetic bone?

4.4 Claim 8 states in part, “comparing the model of macrostructural characteristics of the bone with a subject bone to be reconstructed or grafted”. This does not make sense. The model of macrostructural characteristics of the bone is a mathematical model consisting of equations. How can one compare the mathematical equations written on a paper to the subject bone to be reconstructed or grafted? The specification does not explain how the mathematical model of the bone is compared to the subject bone to be reconstructed or grafted. The model could also a computer model written as software. The claim does not state that. Even if it were a computer

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model, the computer model cannot be compared to a subject bone to be reconstructed or grafted. How do you compare the software in the computer to a bone to be reconstructed or grafted? It is also not clear if the applicant meant to say subject bone to be reconstructed or grafted or a model of the subject bone to be reconstructed or grafted. What is the basis for comparing the model of the bone with the model of subject bone to be reconstructed or grafted?

4.5 Claim 9 states in part, “comparing the model of macrostructural characteristics of the bone with a subject bone to receive screws or prostheses”. This does not make sense. The model of macrostructural characteristics of the bone is a mathematical model consisting of equations. How can one compare the mathematical equations written on a paper to the subject bone or an actual to receive screws or prostheses? The specification does not explain how the mathematical model of the bone is compared to the actual bone. The model could also a computer model written as software. The claim does not state that. Even if it were a computer model, the computer model cannot be compared to an actual bone to receive screws or prostheses. How do you compare the software in the computer to a bone in the human body?

Claims rejected but not specifically addressed are rejected based on their dependency on rejected claims.

5. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the claim in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5.1 Claim 5 states, “A model of macrostructural characteristics of a bone and interactions of the bone with external force comprising at least three orders of hierarchical structural and hierarchical mechanical properties of microstructure of the bone, wherein:

a first order comprises at least one macroscopic region of the bone”.

The statement “three orders of hierarchical structural and hierarchical mechanical properties of *microstructure of the bone* wherein a first order comprises at least *one macroscopic region of the bone*” implies that one of the three orders of the microstructure of the bone includes the macrostructure of the bone. This is inconsistent with specification Paragraph 0003. One of ordinary skill in the art will not be able to build such a model due to the incompatibilities in the definition of the three orders of the microstructure.

5.2 Claim 6 states in part, “comparing the model of macrostructural characteristics of the bone with a subject bone”. The model of macrostructural characteristics of the bone is a mathematical model consisting of equations. It is not possible to compare the mathematical equations written on a paper to the subject bone or an actual or real or human bone. The model could also be a computer model written as software. Even if it were a computer model, the computer model cannot be compared to an actual bone.

Claim 6 states in part, “predicting deformation or fractures of the subject bone based upon the differences in the model of bone and the subject bone”. It is not possible to determine

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differences in the model of the bone and the subject of the bone if the model of the bone is a mathematical model or a software model.

5.3 Claim 7 states in part, “comparing the model of macrostructural characteristics of the bone with a synthetic bone”. The model of macrostructural characteristics of the bone is a mathematical model consisting of equations. It is not possible to compare the mathematical equations written on a paper to the synthetic bone. The model could also be a computer model written as software. Even if it were a computer model, the computer model cannot be compared to the synthetic bone.

5.4 Claim 8 states in part, “comparing the model of macrostructural characteristics of the bone with a subject bone to be reconstructed or grafted”. The model of macrostructural characteristics of the bone is a mathematical model consisting of equations. It is not possible to compare the mathematical equations written on a paper to the subject bone to be reconstructed or grafted. The model could also be a computer model written as software. Even if it were a computer model, the computer model cannot be compared to a subject bone to be reconstructed or grafted.

5.5 Claim 9 states in part, “comparing the model of macrostructural characteristics of the bone with a subject bone to receive screws or prostheses”. The model of macrostructural characteristics of the bone is a mathematical model consisting of equations. It is not possible to compare the mathematical equations written on a paper to the subject bone to receive screws or

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prostheses. The model could also be a computer model written as software. Even if it were a computer model, the computer model cannot be compared to a subject bone to receive screws or prostheses.

Claims rejected but not specifically addressed are rejected based on their dependency on rejected claims.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed inventions are directed to non-statutory subject matter.

7.1 Independent claim 1 recites a model of macrostructural characteristics of a bone and interactions of the bone with external force comprising at least three orders of hierarchical structural and hierarchical mechanical properties of microstructure of the bone. The limitations recited in claim contain a first order, a second order, a third order and assembling components of third and second orders which are all mathematical models or software components. Therefore it appears that the model of macrostructural characteristics of a bone is a set of mathematical equations or software tool which is not statutory subject matter. To be statutory, the claim

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should refer to a system or apparatus comprising hardware elements and software components, wherein the software components would comprise a model of macrostructural characteristics of a bone.

The limitations recited in dependent claims 2-3 contain descriptions of the characteristics of the bone or mechanical properties which are not statutory subject matter.

7.2 Method claims 4-9 are rejected for reciting a process that is not directed to the technological arts.

Regarding claim 4, this claim is directed at a method of predicting deformation and fractures of bone using the model, whereas none of the limitations describe any type of computer-implemented steps. To be statutory, the utility of an invention must be within the technological arts. *In re Musgrave*, 167 USPQ 280, 289-90 (CCPA, 1970). The definition of “technology” is the “application of science and engineering to the development of machines and procedures in order to enhance or improve human conditions, or at least to improve human efficiency in some respect.” (Computer Dictionary 384 (Microsoft Press, 2d ed. 1994)).

Dependent claim 6 depends on Claim 4 but does not add further statutory steps. The limitations recited in claim 6 contain no language suggesting this claim is intended to be within the technological arts.

Regarding claim 5, this claim is directed at a method of identifying the requirements of bone reconstruction and prosthesis using the model, whereas none of the limitations describe any type of computer-implemented steps. To be statutory, the utility of an invention must be within

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the technological arts.

Dependent claims 7-9 depend on Claim 5 but does not add further statutory steps. The limitations recited in claims 7-9 contain no language suggesting these claims are intended to be within the technological arts.

8.1 Claims 1- 3 would be statutory if claim 1 is rewritten as a system or apparatus claim comprising hardware elements and software components, wherein the software components comprise a model of macrostructural characteristics of a bone ..., comprising ...

8.2 Claims 4 and 6 would be statutory if claim 4 is rewritten as a computer implemented method of predicting deformation and fractures of bone using the model...

8.3 Claims 5 and 7-9 would be statutory if claim 5 is rewritten as a computer implemented method of identifying the requirements of bone reconstruction and prosthesis using the model...

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** (“Compact Bone: Numerical simulation of mechanical characteristics”, J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Lakes** (“Materials with structural hierarchy”, Nature, 361, 11 February 1993), and further in view of **Manolagas et al.** (U.S. Patent 6,416,737).

11.1 **Crolet et al.** teaches Compact Bone: Numerical simulation of mechanical characteristics. Specifically, as per claim 1, **Crolet et al.** teaches a model of macrostructural characteristics of a bone and interactions of the bone with external force comprising at least three orders of hierarchical structural and hierarchical mechanical properties of microstructure of the bone, wherein:

- a first order comprises at least one macroscopic region of the bone,
- a second order comprises at least one component representing one or more osteons or lamellae,
- a third order comprises at least one component representing one or more collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, or combinations thereof,

each component is correlated with at least one mechanical property,
components of the third order are assembled to provide a description of components of the second order, and
components of the second order are assembled to provide a description of one or more characteristics of the first order (Page 677, Abstract; Page 677, CL2, Para 1; Page 678, CL2, Para 4 to Page 683, CL2, Para 3).

In addition, **Lakes** also teaches a model of macrostructural characteristics of a bone and interactions of the bone with external force comprising at least three orders of hierarchical structural and hierarchical mechanical properties of microstructure of the bone, wherein:

a first order comprises at least one macroscopic region of the bone,
a second order comprises at least one component representing one or more osteons or lamellae,
a third order comprises at least one component representing one or more collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, or combinations thereof,
each component is correlated with at least one mechanical property,
components of the third order are assembled to provide a description of components of the second order, and
components of the second order are assembled to provide a description of one or more characteristics of the first order (Page 5, Fig. 4; Page 5, Para 1, L1-8; Page 1, Para 2, L1-16; Page 2, Para 3, L1-6; Page 5, Par 1, L12-17). **Lakes** also teaches anisotropy of the lamina and predicting the anisotropic elasticity of the bone.

Crolet et al. does not expressly teach that the model comprises interactions of the bone with external force. **Manolagas et al.** teaches that the model comprises interactions of the bone with external force (CL2, L32-36), as weak bone structure causes the bone to respond incompetently to the mechanical requirements of the skeleton (CL2, L25-29) and it would be desirable to assess how the bone will respond to the external forces. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Manolagas et al.** that included the model comprising interactions of the bone with external force. The artisan would have been motivated because weak bone structure would cause the bone to respond incompetently to the mechanical requirements of the skeleton and it would be desirable to assess how the bone would respond to the external force.

12. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Lakes** ("Materials with structural hierarchy", Nature, 361, 11 February 1993), and further in view of **Manolagas et al.** (U.S. Patent 6,416,737) and **Jiang et al.** (U.S. Patent 6,442,287).

12.1 As per claim 2, **Crolet et al.**, **Lakes** and **Manolagas et al.** teach the model of claim 1. **Crolet et al.** teaches that the bone is compact bone (Page 677, Abstract).

Crolet et al. does not expressly teach that the bone is cancellous bone. **Jiang et al.** teaches that the bone is cancellous bone (CL1, L12-17; CL1, L63-66; CL2, L63 to CL3, L3), as

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analysis of trabecular (cancellous) bone mass and bone structural pattern enables assessment of bone strength and prediction of the risk of fracture (CL2, L25-29). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Jiang et al.** that included the bone being cancellous bone. The artisan would have been motivated because analysis of trabecular (cancellous) bone mass and bone structural pattern would enable assessment of bone strength and prediction of the risk of fracture.

12.2 As per claim 4, **Crolet et al.**, **Lakes** and **Manolagas et al.** teach the model of claim 1. **Crolet et al.** and **Manolagas et al.** also teach the method of using the model as defined in claim 1 as indicated in Paragraph 6.1 above.

Crolet et al. does not expressly teach a method of predicting deformation and fractures of bone using the model. **Jiang et al.** teaches a method of predicting deformation and fractures of bone using the model (CL1, L12-17; CL1, L63-66), as one of the functions of the bone is to resist mechanical failure such as fracture and permanent deformation (CL2, L35-36). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Jiang et al.** that included a method of predicting deformation and fractures of bone using the model. The artisan would have been motivated because one of the functions of the bone has been to resist mechanical failure such as fracture and permanent deformation.

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13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Lakes** ("Materials with structural hierarchy", Nature, 361, 11 February 1993), and further in view of **Manolagas et al.** (U.S. Patent 6,416,737), and further in view of **Winder** (U.S. Patent 6,213,958), **Ascenzi et al.** ("The tensile properties of single osteons", August, 1965), **Ascenzi et al.** ("The shearing properties of single osteons", September, 1971), **Ascenzi et al.** ("The torsional properties of single selected osteons", October 1993), **Ascenzi** ("The estimation of prestress in so-called circularly fibred lamellae", March 1999) and **Ascenzi et al.** ("Pinching in longitudinal and alternate osteons during cyclic loading", November, 1996).

13.1 As per claim 3, **Crolet et al.**, **Lakes** and **Manolagas et al.** teach the model of claim 1. **Crolet et al.** does not expressly teach that the mechanical properties are selected from the group consisting of tension, compression, shear, bending, torsion, prestress, pinching, and cement line slippage. **Winder** teaches that the mechanical properties are selected from the group consisting of compression and bending (CL2, L19-20; CL13, L57-66; CL13, L40-45), as the standard for predicting fracture risks is the accurate measurement of mechanical strength of the bone (CL2, L19-20); and the mechanical properties of the bone such as its strength and toughness depends on its architecture at the microscopic and macroscopic level (CL10, L63-67). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Winder** that included the mechanical properties being selected from the group consisting of compression and bending. The artisan would have been

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motivated because the standard for predicting fracture risks would be the accurate measurement of mechanical strength of the bone; and the mechanical properties of the bone such as its strength and toughness would depend on its architecture at the microscopic and macroscopic level.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of tension. **Ascenzi et al.** (August, 1965) teaches that the mechanical properties are selected from the group consisting of tension (Abstract), as the degree of calcification of the bone increases the modulus of elasticity with additional amounts of calcium compounds; the modulus of elasticity in tension corresponds to that of the collagen; in osteons having longitudinal arrangement of the bundles of fibers in successive lamellae the ultimate tensile strength and modulus of elasticity are greater than in osteons whose bundles in successive lamellae change through an angle of about 90 degrees (Abstract, L7-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (August, 1965) that included the mechanical properties being selected from the group consisting of tension. The artisan would have been motivated because the degree of calcification of the bone would increase the modulus of elasticity with additional amounts of calcium compounds; the modulus of elasticity in tension would correspond to that of the collagen; in osteons having longitudinal arrangement of the bundles of fibers in successive lamellae the ultimate tensile strength and modulus of elasticity would be greater than in osteons whose bundles in successive lamellae changed through an angle of about 90 degrees.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of shear. **Ascenzi et al.** (September, 1971) teaches that the mechanical

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properties are selected from the group consisting of shear (Abstract), as the shearing strength and the modulus of elasticity of osteons increase as the calcification proceeds; the shearing strength in single osteons is markedly lower than the tensile and compressive strength for the samples of same type; and the shearing of the osteons is related to the lamellar structure (Abstract, L9-15).

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (September, 1971) that included the mechanical properties being selected from the group consisting of shear. The artisan would have been motivated because the shearing strength and the modulus of elasticity of osteons would increase as the calcification proceeded; the shearing strength in single osteons would be markedly lower than the tensile and compressive strength for the samples of same type; and the shearing of the osteons would be related to the lamellar structures.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of torsion. **Ascenzi et al.** (October 1993) teaches that the mechanical properties are selected from the group consisting of torsion (Abstract; Page 880, Fig. 4; Page 881, CL1, Para 4), as the longitudinal osteons indicate most resistance to torsional loading; and the transverse osteons have low resistance to torsional loading (Abstract, L8-10). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (October 1993) that included the mechanical properties being selected from the group consisting of torsion. The artisan would have been motivated because the longitudinal osteons would indicate most resistance to torsional loading; and the transverse osteons would have low resistance to torsional loading structures.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of prestress. **Ascenzi** (March 1999) teaches that the mechanical properties are selected from the group consisting of prestress (Abstract, L1-3 and L5-8), because the estimates of prestress allow formulation of hypotheses on prestress formation and lamellar stiffness based on bone ultra- and microstructures (Abstract, L3 and Page 935, CL1, Para 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi** (March 1999) that included the mechanical properties being selected from the group consisting of prestress. The artisan would have been motivated because the estimates of prestress allow formulation of hypotheses on prestress formation and lamellar stiffness based on bone ultra- and microstructures.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of pinching. **Ascenzi et al.** (November, 1996) teaches that the mechanical properties are selected from the group consisting of pinching (Abstract), as pinching occurs in longitudinal osteons consisting of longitudinal fibrils, especially in incompletely calcified ones; in alternate osteons, protected by lamellae containing transversely oriented fibrils, pinching are reduced (Abstract, L10-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (November, 1996) that included the mechanical properties being selected from the group consisting of pinching. The artisan would have been motivated because pinching would occur in longitudinal osteons consisting of longitudinal fibrils, especially in incompletely calcified ones; in alternate osteons, protected by lamellae containing transversely oriented fibrils, pinching would be reduced.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of cement line slippage. **Ascenzi et al.** (September, 1971) teaches that the mechanical properties are selected from the group consisting of cement line slippage (Abstract), as the resistance to shearing of the cementing substance at the boundaries of the osteons may be greater than the resistance of the osteon itself (Abstract, L17-19). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (September, 1971) that included the mechanical properties being selected from the group consisting of cement line slippage. The artisan would have been motivated because the resistance to shearing of the cementing substance at the boundaries of the osteons might be greater than the resistance of the osteon itself.

14. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Lakes** ("Materials with structural hierarchy", Nature, 361, 11 February 1993) and **Manolagas et al.** (U.S. Patent 6,416,737), and further in view of **Copland III et al.** (U.S. Patent 6,333,313) and **Agrawal et al.** (U.S. Patent 5,947,893).

14.1 As per claim 5, **Crolet et al.**, **Lakes** and **Manolagas et al.** teach the model of claim 1. **Crolet et al.** and **Manolagas et al.** teach the method of using the model as described in Paragraph 6.1 above.

Crolet et al. does not expressly teach a method of identifying the requirements of bone reconstruction. **Copland III et al.** teaches a method of identifying the requirements of bone

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reconstruction (CL8, L9-13), as bone reconstruction requires ability to reconstruct defects in bone tissue resulting from various causes (CL8, L10-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Copland III et al.** that included a method of identifying the requirements of bone reconstruction. The artisan would have been motivated because bone reconstruction requires ability to reconstruct defects in bone tissue resulting from various causes.

Crolet et al. does not expressly teach a method of identifying the requirements of prosthesis. **Agrawal et al.** teaches a method of identifying the requirements of prosthesis (Abstract, L1-16), as long term stability of the prosthesis requires bone to form an interlock by growing into the prosthesis at the mating surface (CL1, L43-46). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Agrawal et al.** that included a method of identifying the requirements of prosthesis. The artisan would have been motivated because long term stability of the prosthesis would require bone to form an interlock by growing into the prosthesis at the mating surface.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Lakes** ("Materials with structural hierarchy", Nature, 361, 11 February 1993), and **Manolagas et al.** (U.S. Patent 6,416,737), and further in view of **Jiang et al.** (U.S. Patent 6,442,287) and **Mazess et al.** (U.S. Patent 6,517,487).

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15.1 As per claim 6, **Crolet et al.**, **Lakes**, **Manolagas et al.** and **Jiang et al.** teach the method of claim 4. **Crolet et al.** does not expressly teach comparing the model of macrostructural characteristics of the bone with a subject bone. **Mazess et al.** teaches comparing the model of macrostructural characteristics of the bone with a subject bone (CL1, L22-23; CL3, L48-50; CL4, L57-59; CL9, L9-16; CL9, L50-52; CL9, L66 to CL10, L3), because that allows comparing a characteristic of a reference object such as a model with a measured object such as a bone (CL3, L48-50) and comparing the characteristics of the bone against a standard such as the model (CL9, L9-16) to predict a possible fracture risk (CL2, L13-18). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Mazess et al.** that included comparing the model of macrostructural characteristics of the bone with a subject bone. The artisan would have been motivated because that would allow comparing a characteristic of a reference object such as a model with a measured object such as a bone and comparing the characteristics of the bone against a standard such as the model to predict a possible fracture risk.

Crolet et al. does not expressly teach predicting deformation or fractures of the subject bone based upon the differences in the model of bone and the subject bone. **Mazess et al.** teaches predicting deformation or fractures of the subject bone based upon the differences in the model of bone and the subject bone (CL2, L13-18), because as **Jiang et al.** per one of the functions of the bone is to resist mechanical failure such as fracture and permanent deformation (CL2, L35-36). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Mazess et al.** that included predicting deformation or fractures of the subject bone based upon the differences

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in the model of bone and the subject bone. The artisan would have been motivated because one of the functions of the bone would be to resist mechanical failure such as fracture and permanent deformation.

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Lakes** ("Materials with structural hierarchy", Nature, 361, 11 February 1993), and **Manolagas et al.** (U.S. Patent 6,416,737), and further in view of **Copland III et al.** (U.S. Patent 6,333,313), **Agrawal et al.** (U.S. Patent 5,947,893), **Mazess et al.** (U.S. Patent 6,517,487) and **Wood et al.** (U.S. Patent 6,083,264).

16.1 As per claim 7, **Crolet et al.**, **Lakes**, **Manolagas et al.**, **Copland III et al.** and **Agrawal et al.** teach the method of claim 5. **Crolet et al.** does not expressly teach comparing the model of macrostructural characteristics of the bone with a synthetic bone. **Mazess et al.** teaches comparing the model of macrostructural characteristics of the bone with a synthetic bone (CL1, L22-23; CL3, L48-50; CL4, L57-59; CL9, L9-16; CL9, L50-52; CL9, L66 to CL10, L3), because that allows comparing a characteristic of a reference object such as a model with a measured object such as a synthetic bone (CL3, L48-50) and comparing the characteristics of the synthetic bone against a standard such as the model (CL9, L9-16) to predict a possible fracture risk (CL2, L13-18). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Mazess et al.** that included comparing the model of macrostructural characteristics of the bone with a synthetic

bone. The artisan would have been motivated because that would allow comparing a characteristic of a reference object such as a model with a measured object such as a synthetic bone and comparing the characteristics of the synthetic bone against a standard such as the model to predict a possible fracture risk.

Crolet et al. does not expressly teach designing the synthetic bone to have similar hierarchical structure and hierarchical mechanical properties as the model of bone. **Wood et al.** designing the synthetic bone to have similar hierarchical structure and hierarchical mechanical properties as the model of bone (CL1, L56-59; CL1, L63-64; CL2, L29-33; CL2, L52-57), because synthetic bone is required to have mechanical properties that mimic the natural bone (CL1, L56-59). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Wood et al.** that included designing the synthetic bone to have similar hierarchical structure and hierarchical mechanical properties as the model of bone. The artisan would have been motivated because synthetic bone would be required to have mechanical properties that mimic the natural bone.

17. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Lakes** ("Materials with structural hierarchy", Nature, 361, 11 February 1993), and **Manolagas et al.** (U.S. Patent 6,416,737), and further in view of **Copland III et al.** (U.S. Patent 6,333,313), **Agrawal et al.** (U.S. Patent 5,947,893), **Mazess et al.** (U.S. Patent 6,517,487), **Healy et al.** (U.S. Patent 6,692,532) and **Wood et al.** (U.S. Patent 6,083,264).

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17.1 As per claim 8, **Lakes, Manolagas et al., Copland III et al. and Agrawal et al.** teach the method of claim 5. **Crolet et al.** does not expressly teach comparing the model of macrostructural characteristics of the bone with a subject bone to be reconstructed or grafted. **Mazess et al.** teaches comparing the model of macrostructural characteristics of the bone with a subject bone to be reconstructed or grafted (CL1, L22-23; CL3, L48-50; CL4, L57-59; CL9, L9-16; CL9, L50-52; CL9, L66 to CL10, L3), because that allows comparing a characteristic of a reference object such as a model with a measured object such as a bone (CL3, L48-50) and comparing the characteristics of the bone against a standard such as the model (CL9, L9-16) to predict a possible fracture risk (CL2, L13-18). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Mazess et al.** that included comparing the model of macrostructural characteristics of the bone with a subject bone to be reconstructed or grafted. The artisan would have been motivated because that would allow comparing a characteristic of a reference object such as a model with a measured object such as a bone and comparing the characteristics of the bone against a standard such as the model to predict a possible fracture risk.

Crolet et al. does not expressly teach reconstructing or grafting the subject bone based upon the hierarchical structural and mechanical properties of the model of bone. **Healy et al.** teaches reconstructing or grafting the subject bone based upon the hierarchical structural and mechanical properties of the model of bone (CL1, L4-6; CL7, L50-55; CL9, L33-35; CL9, L41-48; CL10, L26-28), because as per **Wood et al.** synthetic bone is required to have mechanical properties that mimic the natural bone (CL1, L56-59). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.**

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with the method of **Healy et al.** that included reconstructing or grafting the subject bone based upon the hierarchical structural and mechanical properties of the model of bone. The artisan would have been motivated because synthetic bone would be required to have mechanical properties that mimic the natural bone.

18. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Lakes** ("Materials with structural hierarchy", Nature, 361, 11 February 1993), and **Manolagas et al.** (U.S. Patent 6,416,737), and further in view of **Copland III et al.** (U.S. Patent 6,333,313), **Agrawal et al.** (U.S. Patent 5,947,893), **Mazess et al.** (U.S. Patent 6,517,487) and **Lee et al.** (U.S. Patent Application 2002/0136696).

18.1 As per claim 9, **Lakes**, **Manolagas et al.**, **Copland III et al.** and **Agrawal et al.** teach the method of claim 5. **Crolet et al.** does not expressly teach comparing the model of macrostructural characteristics of the bone with a subject bone to receive screws or prostheses. **Mazess et al.** teaches comparing the model of macrostructural characteristics of the bone with a subject bone to receive screws or prostheses (CL1, L22-23; CL3, L48-50; CL4, L57-59; CL9, L9-16; CL9, L50-52; CL9, L66 to CL10, L3), because that allows comparing a characteristic of a reference object such as a model with a measured object such as a bone (CL3, L48-50) and comparing the characteristics of the bone against a standard such as the model (CL9, L9-16) to predict a possible fracture risk (CL2, L13-18). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the

method of **Mazess et al.** that included comparing the model of macrostructural characteristics of the bone with a subject bone to receive screws or prostheses. The artisan would have been motivated because that would allow comparing a characteristic of a reference object such as a model with a measured object such as a bone and comparing the characteristics of the bone against a standard such as the model to predict a possible fracture risk.

Crolet et al. does not expressly teach determining placement of the screws or the prostheses in the subject bone based upon the hierarchical structural and mechanical properties of the model of bone. **Lee III et al.** teaches determining placement of the screws or the prostheses in the subject bone based upon the hierarchical structural and mechanical properties of the model of bone (Page 8, P0094, L2-4), because that allows the screws to firmly anchor the prosthesis in place (Page 9, P0104, L11-13); and the prosthesis to hold the bone in place (Page 8, P0094, L2-4). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Lee III et al.** that included determining placement of the screws or the prostheses in the subject bone based upon the hierarchical structural and mechanical properties of the model of bone. The artisan would have been motivated because that would allow the screws to firmly anchor the prosthesis in place; and the prosthesis to hold the bone in place.

Response to Arguments

19. Applicant's arguments filed on November 15, 2004 have been fully considered. The arguments with respect to 103 (a) rejections are not persuasive.

19.1 As per the applicants' argument that "Crolet also does not assemble groups of osteons into a model of macroscopic properties of an entire bone, e.g., a femur; accordingly, Crolet disregards the dynamic hierarchy of bone structure because it makes unrealistic estimates of structure (e.g., "averaging" osteon structure) and mechanical properties (e.g., assuming linear elasticity); the lack of recognition and use of the hierarchical structural and mechanical properties limits the Crolet model", the examiner respectfully disagrees.

Crolet et al. teaches a model of macrostructural characteristics of a bone and interactions of the bone with external force comprising at least three orders of hierarchical structural and hierarchical mechanical properties of microstructure of the bone (Page 677, Abstract; Page 677, CL2, Para 1; Page 678, CL2, Para 4 to Page 683, CL2, Para 3).

19.2 As per the applicants' argument that "Manolagas does not suggest including properties of the microstructure or the interactions of bone with external force into a macrostructural model of bone. Manolagas in no way suggests including orders of hierarchy, corresponding properties, or the microstructural characteristics of bone with external force into a model of macrostructural properties of bone", the examiner has used **Manolagas** only to teach that the model comprises interactions of the bone with external force.

Manolagas et al. teaches that the model comprises interactions of the bone with external force (CL2, L32-36), as weak bone structure causes the bone to respond incompetently to the mechanical requirements of the skeleton (CL2, L25-29) and it would be desirable to assess how the bone will respond to the external forces.

19.3 As per the applicants' argument that "Crolet and Manolagas do not disclose inclusion of a complete "hierarchical structure and hierarchical mechanical properties of microstructure of bone" into a model, nor do they include the behavior of bone in response to external forces. Crolet and Manolagas further do not delineate the first, second, and third orders of bone wherein each component of the orders is "correlated with at least one mechanical property," and where "components of the third order are assembled to provide a description of components of the second order, and components of the second order are assembled to provide a description of one or more characteristics of the first order, including at least one interaction with an external force", the examiner respectfully disagrees.

Crolet et al. teaches a model of macrostructural characteristics of a bone and interactions of the bone with external force comprising at least three orders of hierarchical structural and hierarchical mechanical properties of microstructure of the bone, wherein:

- a first order comprises at least one macroscopic region of the bone,
- a second order comprises at least one component representing one or more osteons or lamellae,
- a third order comprises at least one component representing one or more collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, or combinations thereof,
- each component is correlated with at least one mechanical property,
- components of the third order are assembled to provide a description of components of the second order, and

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components of the second order are assembled to provide a description of one or more characteristics of the first order (Page 677, Abstract; Page 677, CL2, Para 1; Page 678, CL2, Para 4 to Page 683, CL2, Para 3).

In addition, **Lakes** also teaches a model of macrostructural characteristics of a bone and interactions of the bone with external force comprising at least three orders of hierarchical structural and hierarchical mechanical properties of microstructure of the bone, wherein:

- a first order comprises at least one macroscopic region of the bone,

- a second order comprises at least one component representing one or more osteons or lamellae,

- a third order comprises at least one component representing one or more collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, or combinations thereof,

- each component is correlated with at least one mechanical property,

- components of the third order are assembled to provide a description of components of the second order, and

components of the second order are assembled to provide a description of one or more characteristics of the first order (Page 5, Fig. 4; Page 5, Para 1, L1-8; Page 1, Para 2, L1-16; Page 2, Para 3, L1-6; Page 5, Par 1, L12-17). **Lakes** also teaches anisotropy of the lamina and predicting the anisotropic elasticity of the bone.

19.4 As per the applicants' argument that "Jiang in no way suggest the desirability and thus the obviousness of making the model of cancellous bone", the examiner respectfully disagrees.

Jiang et al. teaches that the bone is cancellous bone (CL1, L12-17; CL1, L63-66; CL2, L63 to CL3, L3), as analysis of trabecular (cancellous) bone mass and bone structural pattern enables assessment of bone strength and prediction of the risk of fracture (CL2, L25-29).

19.5 As per the applicants' argument that "Winder does not account for, nor does Winder teach, that the mechanical properties of bone also vary with respect to the discrete hierarchical levels of bone architecture; instead, Winder discloses a processing method that is sensitive to the structural changes in bone architecture, but only sensitive to the macro mechanical properties of bone; Winder does not disclose what level or order of microstructure it is able to detect, and whether its data acquisition system actually accounts for the third order of bone, e.g., collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, and combinations thereof, or even the non-homogenous second order of bone; thus, while acknowledging that bone has microstructural properties which are not homogeneous or isotropic, Winder does not make use of this information to provide a model", the examiner has used **Winder** only to teach mechanical properties of bending.

19.6 As per the applicants' argument that "Crolet makes no suggestion to modify its simplified mathematical model by inclusion of mechanical properties, e.g., tension and prestress, shearing strength, torsional properties, and pinching", the examiner has used different **Ascenzi** references to teach these properties as shown in Paragraph 13.1 above.

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19.7 As per the applicants' argument that "the combination of teachings of Crolet (an over-simplified and highly unrealistic bone model), with Manolagas (bisphosphonate administration), Copeland III (oxytocin administration), and Agrawal (a method of making a porous prosthesis) in no way suggest the desirability or systematic steps, and thus the obviousness, of the method incorporating use of a model of the macrostructural properties of a bone, respecting hierarchical structure, hierarchical mechanical properties of microstructure, and interactions of bone with external force", the examiner respectfully disagrees.

Crolet et al. and **Manolagas** teach the desirability or systematic steps, and thus the obviousness, of the method incorporating use of a model of the macrostructural properties of a bone, respecting hierarchical structure, hierarchical mechanical properties of microstructure, and interactions of bone with external force as described in Paragraphs 11. 1 and 19.1 above.

In addition, **Lakes** also teaches a model of macrostructural characteristics of a bone and interactions of the bone with external force comprising at least three orders of hierarchical structural and hierarchical mechanical properties of microstructure of the bone, wherein:

- a first order comprises at least one macroscopic region of the bone,
- a second order comprises at least one component representing one or more osteons or lamellae,
- a third order comprises at least one component representing one or more collagen bundles, hydroxyapatite crystallites, mucopolysaccharides, or combinations thereof,
- each component is correlated with at least one mechanical property,
- components of the third order are assembled to provide a description of components of the second order, and

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components of the second order are assembled to provide a description of one or more characteristics of the first order (Page 5, Fig. 4; Page 5, Para 1, L1-8; Page 1, Para 2, L1-16; Page 2, Para 3, L1-6; Page 5, Par 1, L12-17). **Lakes** also teaches anisotropy of the lamina and predicting the anisotropic elasticity of the bone.

Conclusion

ACTION IS FINAL

20. Applicant's amendments necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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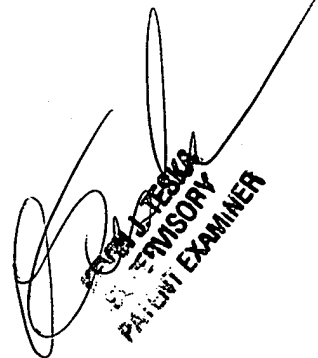
21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 571-272-3717. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska, can be reached on 571-272-3716. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

K. Thangavelu
Art Unit 2123
February 10, 2005



KEVIN TESKA
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PATENT EXAMINER